Applic. No. 10/718,315
Response dated July 10, 2006
Reply to Office action of March 9, 2006

GLM-1042 IT

Remarks:

Applicants appreciatively acknowledge the Examiner's confirmation of receipt of applicants' claim for priority under 35 U.S.C. § 119(a)-(d) and the allowance of claims 10 to 21.

Reconsideration of the application is requested.

Claims 1 to 42 remain in the application. Claims 10 to 22 are subject to examination and claims 1 to 9 and 23 to 42 have been withdrawn from examination.

In items 2 to 3 on pages 2 to 3 of the above-identified Office action, claim 22 has been rejected as being obvious over United States Patent No. 5,697,948 to Marin et al. (hereinafter "Marin") in view of United States Patent No. 6,143,014 to Dehdashtian et al. (hereinafter "Dehdashtian") under 35 U.S.C. § 103.

As will be explained below, it is believed that the claim was patentable over the cited art in its original form and, therefore, the claim has not been amended to overcome the references.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful.

Claim 22 calls for, *inter alia*, a delivery system for releasing a prosthesis having anchoring stents, including:

at least one releasing balloon catheter having:

an inflatable balloon removably inserted within a prosthesis; and

a self-supporting tube defining a lumen and having a first diameter and two opposing ends;

at least one guiding balloon catheter having:

a dilator defining an inner lumen having an inner diameter sized to pass the self-supporting tube of the release catheter therethrough, the dilator having:

a proximal portion having an outer diameter larger than the inner diameter of the inner lumen; and

a median portion having a substantially constant outer diameter smaller than the outer diameter of the proximal portion; and

a tubular sheath having:

an inner diameter at least as great as the outer diameter of the median portion of the dilator and less than the second diameter of the cup connection; and

a terminal outer balloon disposed at a distal end of the sheath; and

at least one introducer for introducing the balloon guiding catheter into a patient.

The present invention includes a guiding balloon catheter 2, 3 (see FIG. 4) and a separate releasing balloon catheter 1 (see FIGS. 1 to 5). The guiding balloon catheter 2, 3 has an outer balloon 33 that, as shown in FIGS. 6 to 11, is inflated to maintain a position of the catheter 2, 3 in a vessel. In particular, hemostasis can be provided using this compliant balloon because it is external to the guide sheath.

Claim 22 includes dimensions such that the terminal outer balloon 33 is an outer balloon. Specifically, the outer balloon 33 of the tubular sheath 3 is disposed at one of the distal ends of the sheath 3 (see FIG. 4). This tubular sheath 3 has an inner diameter D3i at least as great as the outer diameter of the median portion D2e of the dilator 2 of the guiding balloon catheter 2, 3. The dilator 2 has an inner lumen with a diameter D2i sized to pass therethrough the tube 11 of the releasing balloon catheter 1.

Simply put, the tube 11 of the releasing balloon catheter 1, 5 fits within the dilator 2, and the dilator 2 fits within the sheath 3. Thus, the outer balloon 33 is an external balloon of the guiding sheath 3.

The outer balloon 33 on the guiding sheath 3 does not deploy a stent - it provides a stop to blood backflow. The guiding sheath 3 allows passage of the tube 11 of the releasing balloon catheter. It is the inflatable balloon 13, 53 on the releasing balloon catheter 1, 5 that is inflated to release the stent graft 100 (it is not the outer balloon 33). The stent graft 100, the releasing balloon catheter 1, 5, and the guiding balloon catheter 2, 3 are three different components.

Marin, in contrast, relates to an interface of the delivery catheter, two balloons, and the guiding sheath balloons. Marin allows for a placement of two balloons in sequence and passing a unique guidewire in the two.

The present invention is completely different from such a configuration because the guiding sheath 3 has an *external* balloon - it does not protrude from the inside. Thus, the sheath 2 can host the tube of the delivery balloon 13, 53 *in reverse fashion* as compared to the Marin system.

Marin has various advantages that direct one having ordinary skill in the art away from the present invention. First, Marin desires to avoid use of a mandrel (one exists in the present

invention). Marin also pressurizes the guide sheath with the inner balloon - a function that is irrelevant to the present invention and cannot provide hemostasis around a sheath to avoid back flow into an aneurysm sac from the iliac arteries, for example. Second, Marin desires to reduce a thickness of the sheath wall by pressurizing it with the inner balloon. This feature is also irrelevant to the present invention. Finally, Marin desires to allow the stent and guiding sheath to be advanced *together* and not the guiding sheath first and the stent/graft thereafter. In the present invention, there are two different, sequential steps.

The Marin device is, simply, a sheath having an *inner* balloon performing different functions and solving different problems than the present invention. First, the Marin device allows passage of stents and endo-grafts therethrough and is directed to provide insertion of the guiding sheath and a stent/graft *together*. The guiding balloon catheter of the present invention provides *passage* to retrieve a balloon tube and the hypotube of the releasing balloon. A stent or endograft or guidewire do not pass through the sheath. Second, the Marin device reduces the likelihood of accidental arterial injury or dislodgment of thrombus or plaque through a" balloon (which) extends partially

from the distal end of the guide sheath and, when it is inflated, provide a tapered surface at the distal end of the guide sheath which merges smoothly with the outer surface of the guide sheath..." This is a problem different from that addressed by the present invention.

Clearly, Marin does not show a delivery system as recited in claim 22 of the instant application.

The Examiner combines Marin with Dehdashtian to make up for Marin lack of a dilator and an introducer. However, adding the disclosure of Dehdashtian to Marin does not make up for the deficiencies that Marin has when compared to the features of claim 22 as set forth above. Thus, the combination of these two references cannot, by definition, suggest the features of claim 22.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the

applicant". *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be **'clear and particular.'**" *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants respectfully believe that there is no "clear and particular" teaching or suggestion in Marin to incorporate the features of Dehdashtian, and there is no teaching or suggestion in Dehdashtian to incorporate the features of Marin.

In establishing a *prima facie* case of obviousness, it is **incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The Examiner has not provided the requisite reason why one of ordinary skill in the art would have been led to modify Marin or Dehdashtian or to combine Marin's and Dehdashtian's teachings to arrive at the claimed vascular repair device invention.

The Examiner has the burden for satisfying the above requirements. But, the Examiner has not shown the requisite motivation from some teaching, suggestion, or inference in Marin or Dehdashtian or from knowledge available to those skilled in the art.

Further, the Dehdashtian introducer sheath is in no way comparable to the present sheath. The introducer sheath (i.e., the guiding sheath) of the present invention is different from the Dehdashtian device because the guiding sheath has an external balloon 33. It is more of a haemostatic balloon than an introducer because only the tube of the releasing balloon is passed therethrough.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art.

Finally, applicants appreciatively acknowledge the Examiner's statement that claims 10 to 21 are allowable.

In view of the foregoing, reconsideration and allowance of claims 10 to 22 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of one (1) month pursuant to Section 1.136(a) in the amount of $120.00 in accordance with Section 1.17 is enclosed herewith.

Please charge any fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Gregory L. Mayback, P.A., No. 503836.

Respectfully submitted,

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For Applicants
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Date: July 10, 2006

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